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Comparative effectiveness of interventions for treating the psychological consequences of sexual abuse in children and adolescents (Protocol)

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[Intervention Protocol]

Comparative effectiveness of interventions for treating the psychological consequences of sexual abuse in children and adolescents

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the relative effectiveness of psychosocial therapies, compared to other treatments or no treatment controls, to overcome psychological sequelae of sexual abuse in children and young people up to 18 years of age.

Secondary objectives

- To rank psychotherapies according to their effectiveness.
- To compare different 'doses' of the same intervention.
- To explore differences between subgroups of participants and assess the impact of moderator variables on treatment outcomes.

BACKGROUND

Description of the condition

The National Institute for Health and Clinical Excellence (NICE) in the UK defines child sexual abuse (CSA) as follows.
"[CSA] involves forcing or enticing a child or young person to take part in sexual activities, not necessarily involving a high level of violence, whether or not the child is aware of what is happening. The activities may involve physical contact, including assault by penetration (for example, rape or oral sex) or non-penetrative acts such as masturbation, kissing, rubbing and touching outside of clothing. They may also include non-contact activities, such as involving children in looking at, or in the production of, sexual images, watching sexual activities, encouraging children to behave in sexually inappropriate ways, or grooming a child in preparation for abuse (including through the internet). Sexual abuse is not solely perpetrated by adult males. Women can also commit acts of sexual abuse, as can other children." (NICE 2017, p 46 to 7).
Child sexual exploitation is increasingly recognised as a particu-

lar form of child sexual abuse, in which an imbalance of power between a child or young person and others is used "to coerce, manipulate or deceive a child or young person under the age of 18 into sexual activity (a) in exchange for something the victim needs or wants, and/or (b) for the financial advantage of increased status of the perpetrator or facilitator." (NICE 2017, p 42 to 3). Exploitation may occur even in circumstances where the sexual activity appears consensual and it can occur through the use of technology.

Prevalence

Estimates of the prevalence of CSA vary widely for a number of reasons. Definitions may differ according to the country where the problem is being studied, data may vary in their availability and quality, and there are methodological differences between studies and differences in context where victims and perpetrators live; for example, conditions of war and social unrest and injustice; low-, middle- or high-income countries, etc. (Gilbert 2009; Latzman 2017; Singh 2014).

Aiming to describe global prevalence rates of CSA, Barth and colleagues conducted a meta-analysis of studies reporting cases of four predefined types of CSA (forced intercourse, mixed sexual abuse, non-contact abuse, and contact abuse) in children and adolescents under 18 years of age (Barth 2013). Studies were excluded when the country was not reported (indicative of low-quality reporting) and the sample size was smaller than 1000 (low statistical precision). The 55 included studies were published between 2002 and 2009 and covered 24 countries: 16 studies were conducted in Asia, 14 in North America, 11 in Europe, 9 in Africa and 5 in Central and South America. For girls, the review authors reported pooled prevalence rates for forced intercourse, mixed sexual abuse, non-contact abuse and contact abuse of 9%, 15%, 31% and 13%, respectively; for boys, the figures were 3%, 8%, 17% and 6%, respectively.

Barth and colleagues also explored contextual (geographical region, level of development assessed using the Human Development Index (United Nations Development Programme 2009)) and methodological variables that might explain the heterogeneity of the prevalence estimates between studies (Barth 2013). The reviewers found no statistical differences in prevalence rates across studies conducted in different regions or degree of development of the country.

Consequences of CSA

As well as the physical and psychological trauma that may be associated with penetrative sexual abuse (e.g. vulval or anal sores, infections, higher risk of sexually transmitted diseases), children who are sexually abused are at risk of adverse effects in many areas of their development and functioning (Fisher 2017). Child sexual abuse is associated with increased risk of poor physical and mental health, impeded cognitive development, and emotional and behavioural problems. Long and intense experiences of stress during childhood disturb brain architecture, affect metabolic mechanisms and the immune system, and increase the risk of stress-related chronic illnesses such as hypertension, cardiovascular diseases, and mental ill health (Allnock 2012). Lifetime consequences can include poorer educational outcomes, low socioeconomic status, unemployment, and revictimisation (Allnock 2012; Fisher 2017; Herrmann 2014; McEwen 2007; NSCDC 2007; Woods 2005).

Post-traumatic stress disorder (PTSD), sexualised behaviour, and internalising and externalising problems have been identified as the most common psychological problems following sexual abuse (Fergusson 1999; Harvey 2010; MacMillan 2009; Putnam 2003; Trask 2011). According to the criteria of the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders (*DSM-5), a child meets the criteria for a PTSD diagnosis if he or she demonstrates concurrence of at least one symptom of re-experiencing the traumatic experience, three or more symptoms of avoidant behaviours, and two or more symptoms of autonomic hyperarousal (Deblinger 1989; DSM-5). Sexualised behaviour is characterised by sexualised play with dolls, putting objects into anuses or vaginas, excessive or public masturbation, seductive behaviour, requesting sexual stimulation from adults or other children, and age-inappropriate sexual knowledge. Internalising problems include social withdrawal, depression, fearfulness, inhibition, and over-controlled behaviour; while externalising problems include aggression, hyperactivity, and antisocial and under-controlled behaviour (Kendall-Tackett 1993; Trask 2011). Pre-school-age children (birth to six years old) are more likely to suffer anxiety, nightmares, PTSD, internalising and externalising problems and sexualised behaviours; school-age children (7 to 12 years old) are more likely to have school problems, hyperactivity, and aggressive and regressive behaviours; and adolescents (13 to 18 years old) are more likely to harm themselves, suffer depression, and engage in substance abuse and criminal behaviour (Kendall-Tackett 1993).

The consequences of CSA represent a high economic burden for societies and governments. In the UK, the annual cost of child sexual abuse is GBP 3.2 billion, including (in millions): child depression (GBP 1.6); child suicide (GBP 1.9); adult mental health (GBP 162.7); adult physical health, alcohol and drug misuse (GBP 15.4); criminal justice system (GBP 149); services for children (GBP 124); and productivity losses (GBP 2700) (Saied-Tessier 2014). In the USA, the average cost per victim of child maltreatment in 2012 was estimated to be USD 210,200 including: childhood health care costs (USD 32,248), adult medical costs (USD 10,530), productivity losses (USD 144,360), child welfare costs (USD 7720), criminal justice costs (USD 6747) and special education costs (USD 7999) (Fang 2012). In 2016, the lifetime costs attributable to child maltreatment in Australia were estimated at AUD 17.4 billion, including (in millions): health system costs (AUD 3.301), special education costs (AUD 196.4), criminal justice system costs (AUD 904.2), child protection system (AUD

818.2), productivity losses (AUD 2529.9), loss of quality of life related to mental health (AUD 16,601.9) and premature mortality (unfulfilled life expectancy) (AUD 757.2) (McCarthy 2016).

Description of the intervention

Psychosocial or psychotherapeutic interventions used to treat the consequences of sexual abuse amongst children and young people come from different theoretical orientations: psychodynamic or psychoanalytic; cognitive-behavioural; systemic; and humanistic theory (Sánchez-Meca 2011). The main characteristics of interventions drawing from these are described below. Treatment delivery, as well as overall suitability and accessibility, may vary according to the patients' age, symptoms, severity of impairment, settings, contexts, training of therapists, availability of mental health services for victims, and other variables.

Psychodynamic therapies

The term psychodynamic is used as a general term for all forms of psychoanalysis and psychoanalytically-derived psychotherapy. Psychodynamic theories centre on the use of 'transference' to study unconscious and conscious aspects of the mind (Shemilt 2007). Psychoanalysis is a clinical and theoretical discipline originating from Sigmund Freud's proposition that unconscious mental forces, called instincts or 'instinctual drives', motivate and shape human perceptions and behaviour (Likierman 1999). Psychoanalysis is based upon exploration of the unconscious, resulting in insights gained by the analysis of the transference relationship. 'Transference' refers to the patient's unconscious motives and personality structure, as expressed in the relationship with the therapist, and can be defined as a re-enacted memory of earlier situations, developmental stages and relationships. Unconscious traces of these memories and associated ideas and emotions are believed to shape the patient's perception of the therapist and their behaviour towards him or her (Prochaska 1999; Shemilt 2007).

Following Freud, many diverging psychodynamic theories were developed by emphasising different aspects of personal development as the core organising principles for personality and psychopathology. Psychodynamic child psychotherapies, as modern variants of child psychoanalysis, are briefer and goal directed, incorporating into their theories a psychoanalytic understanding of pathology and its development. The primary focus of child psychotherapy is the strengthening of ego defences and the amelioration of specific symptoms or problem areas. Concurrent with individual therapy for the child, the parents or carers may be engaged in psychotherapy. Close attention is paid to contextual or environmental issues and their active modification (Harper 1995; Kegerreis 2010).

Cognitive behavioural therapy (CBT) interventions and Trauma-focused CBT (TF-CBT)

CBT interventions are multi-component interventions that draw primarily on cognitive theories of learning, with particular attention on how the meaning we attribute to events mediates their impact upon us. They also incorporate gradual exposure (both imaginal and in vivo), modelling and behaviour rehearsal. More broadly, CBT treatments generally draw on a range of theories, including systems theory, attachment theory and neurodevelopmental theories of trauma, as well as theories of child and adolescent development. TF-CBT is one of the most widely used cognitive behavioural interventions. Developed by Esther Deblinger, Judith Cohen and Anthony Mannarino (see Cohen 2006; Deblinger 1996), it takes the form of a sequential programme comprising three phases of similar length (see Cohen 2018 for a full description) and summarised in the acronym PRACTICE:

- **Phase 1** Stabilisation and skills enhancement. This includes:
  - **p**sychoeducation about the impact of sexual abuse (giving parents and children information about sexual abuse, such as why it happens, who is affected, how children feel and the impact it can have on them and their parents), and parenting skills to help parents support their children and manage the 'fall-out' that sexual abuse can have in relation to child behaviour problems;
  - **r**elaxation training, to reduce and manage stress;
  - **a**ffective skills, to assist in managing the emotional consequences of trauma (i.e. dysregulation); and
  - **c**ognitive processing skills, to help parents and children understand the relationship between thoughts, feelings and behaviours, and to develop more accurate and helpful thoughts.
- **Phase 2**
  - **t**rauma narration and processing. In this phase children and parents are helped to develop a 'trauma narrative' and engage in processing it cognitively.
- **Phase 3** Consolidation. This last phase encompasses:
  - **i**n vivo exposure;
  - **c**onjoint sessions with parents and children to improve communication, both generally and in relation to the sexual abuse; and
  - **e**nhancing safety.

This structured, yet flexible programme (e.g. if children are at risk, issues of safety may be dealt with early on in the programme), is typically delivered in 8 to 16 sessions, in either individual or group format, with separate sessions for carer and child, combined with conjoint sessions. When implemented with young people in residential settings, the length of treatment can extend to some 25 sessions.

Eye-Movement Desensitisation and Reprocessing (EMDR)

Eye-Movement Desensitisation and Reprocessing (EMDR) is a therapeutic treatment that was originally designed to treat psychological distress associated with trauma (Shapiro 1989). Since its inception, EMDR has been shown to be an effective therapy with a strong research base (Chen 2018); it is one of only two treatments approved by NICE for symptoms of PTSD including children over five years old (NICE 2018), and it is recognised by the World Health Organization (WHO) as an effective therapy for people who have experienced trauma (WHO 2013).

During EMDR therapy a three-pronged approach is used, which includes questions regarding the aetiology of the traumatic event (past), the triggers of PTSD symptoms (present), and the installation of future templates related to adequately coping with upsetting events (future) (Shapiro 2001). With EMDR therapy, these items are addressed using an eight-phase treatment (see Shapiro 2001 for a full description). Through the process of EMDR, each negative cognition is extracted and substituted with a healthy positive cognition for a traumatic incident. The physical dissonance associated with that traumatic memory is transformed or subsequently relieved. The Subjective Units of Disturbance (SUD) scale is used to measure the level of subjective disturbance. Substantial decreases in the levels of disturbance reflect the attainment of desensitisation.

During the EMRD session, the client is instructed to focus on recalling a traumatic memory in brief sequential doses, while simultaneously focusing on an external stimulus such as tracking the therapist's finger being waved back and forth in front of the client in a precisely prescribed manner (though a variety of other stimuli, including hand-tapping and audio stimulation, are often used) (Shapiro 1993; Shapiro 2007). The Validity of Cognition (VOC) scale is used to measure the strength of the faulty negative cognition. The process of bilateral stimuli is repeated until the individual consigns a positive thought in place of the older negative thought. The number of sessions depends on the severity of traumatic event and negative memories. EMDR therapy can be modified dependent upon the specific needs and developmental stage of the child or adolescent. For some children, especially very young children or those who may struggle to talk about the traumatic event, pictures can be used instead of words. In the course of EMDR therapy, unprocessed memories of traumatic experiences, stored in neural networks, become linked with the adaptively processed memories of positive experiences. This is a method called 'reprocessing' (Shapiro 2007).

Systemic therapies

Systemic therapies view families as contexts that ameliorate or reinforce children's psychological distress resulting from abuse either perpetrated inside or outside the family (Carr 2006; Dallos 2010). Generally, systemic therapies maintain that: (1) the clients' difficulties and needs should be addressed within the context and the relational system in which they are; (2) the system has circular and evolving patterns of behaviour; (3) beliefs and behaviours are the basis of the system's narratives; (4) the members of the system construe what happens from their own frame of reference; (5) meanings emerge from social interactions and context; (6) the therapist should adopt different stances of power with the client's family and the therapeutic relationship; (7) during the therapy, the therapist and the system construct reality; (8) the therapist should be self-reflective on his or her own constructions; and (9) the therapists should have a positive view of the family and stress its strengths in order to work as a unit (Karakurt 2014; Lorås 2017).

Systemic therapies can be delivered in structured, strategic and social constructivist models. Each model makes different hypotheses about the roots of the family's problems and thereby the ways in which the therapy is expected to lead to changes (Tickle 2016). However, similar treatment techniques, which are employed across models include (Lorås 2016):

- adaptive reframing of situations, using metaphors and externalisation of thoughts, feelings and beliefs;
- creation of alternative stories of the family's problems in which the problem is not the dominant trait of the system;
- a focus on strengths and solutions: therapists encourage family members to seek change with their own resources and efforts; and
- reflecting: the therapy is seen as a safe space where family members feel free to listen, acknowledge and discuss different positions.

The therapy, which can last several weeks to several months, focuses on improving the family's functioning as a unit, and involves different elements such as psychoeducation, developing maps of family patterns, and narrative techniques (Carr 2006; Dallos 2010; Goepfert 2015; Solomon 2012; Spain 2017).

Person-centred therapy

Person-centred therapy emerged in the 1950s and 1960s as a response to the behavioural and psychoanalytic approaches. Humanistic theory proposed a shift from viewing a lack of free will in human actions, behaviours, cognitions and decisions, towards viewing a client capable of self-determination. Person-centred therapy is based on the premise that clients have an inherent tendency to develop their potential (termed 'self-actualisation'), and incorporates the notion that it is the therapeutic relationship that is curative in its own right (Rogers 1951). The previous history of the child's emotional problems is unimportant. The manifestation of the problem in the moment and a focus on present feelings is considered the most important focus for therapy. With its fundamental postulate that play is the child's natural medium of expression, non-directive play therapy offers the child the opportunity to 'play out' their feelings, problems and difficulties, and therefore to develop a more positive image of themselves rather than relying on external 'conditions of worth' (Axline 1947). It is by the constant recognition and clarification of the emotions in the non-directive

(play) therapy that the child's (or young person's) insights into the feelings that motivate behaviour and self-definition can emerge.
The young person's free expression of themselves is facilitated by communicating three basic therapist attitudes: (1) empathy; (2) genuineness; and (3) unconditional positive regard. The primary therapeutic objective is to provide the child or young person with the maximum opportunity to express their feelings, so that these can be recognised and clarified, so the child is eventually enabled to identify their own feelings and thereby to become master of them.
The treatment is delivered in individual format and the length varies on the basis of the client's needs (Cain 2001; Hofmann 2017).

How the intervention might work

Psychodynamic therapies

In psychodynamic therapies the containment offered by a positive transference relationship with the therapist is thought to facilitate the expression of inner conflicts and the overcoming of resistance. For CSA victims, the defences available to the child to deal with abuse will depend on the maturity of the child at the time of the abuse, as well as the capacity of adults to hear and act on any disclosure. In cases where there has not been suitable intervention at the time, young people are thought to exhibit psychological symptoms and inappropriate behaviour(s), as a result of a reliance on very primitive defence mechanisms (Kegerreis 2010; Lanyado 1999).
The early stages of psychotherapy with sexually abused children focus on building basic trust. The child or young person is encouraged to express their thoughts and fantasies as they occur, and to present them in whatever way they choose (verbally or non-verbally, or both) using toys, drawings or dramatisation (Harper 1995). While the defences that they have organised must be respected, therapists frequently use a range of psychoanalytic procedures, such as 'clarification' and 'interpretation', to help the child understand the significance of certain behaviours (Horne 1999; Kegerreis 2010). Clarifications may simply involve descriptions of the patient's behaviour or a repetition of the child's statements, to get the child to elaborate on what he or she is doing. At other times they are designed to help the child understand and label feelings of which he or she may be unaware. The technique used by most therapists is 'interpretation' of the child's play or verbal statements, designed to bring unconscious material to awareness. The therapist comments on the relationships between thoughts, feelings and behaviours, or poses tentative hypotheses regarding the 'meaning' of certain behaviours (Harper 1995; Horne 1999; Prochaska 1999).
Through the therapist's interpretations, unhelpful (i.e. immature) defences can be noted, verbalised and slowly explored, and their meaning analysed when therapy is well established. In the last phases of therapy, the insights that have come about from interpretation of resistance and transference are 'worked through'. The gradual attainment of insight is seen to be a precursor of significant therapeutic change expressed with a strengthened and more mature ego functioning that is better able to cope with the demands of intrapsychic conflicts at the end of therapy (Harper 1995; Horne 1999; Kegerreis 2010).

Cognitive behavioural therapy interventions (CBT) and Trauma-focused CBT (TF-CBT)

To some extent the description of TF-CBT provides an indication of how this intervention might work, so we expand a little on the key 'ingredients' in this section.
The trauma of sexual abuse, like other trauma, can profoundly and adversely impact the way that children see themselves, the world and their future. Sexual abuse can also adversely impact family cohesiveness and undermine a parent's ability to provide adequate support to affected children. CBT interventions, therefore, include strategies to support or improve family functioning and parenting capacity by addressing parental distress caused by what has happened and how the child is responding.
Psychoeducation is seen as an important component of this support, for both parents and older children, in order to make sense of why children might be thinking, feeling and behaving in particular ways (see Phase 1 of TF-CBT above under Description of the intervention). Relaxation strategies provide a means of managing the physiological consequences of trauma.
Parenting strategies are designed to help parents managing the behaviour problems that are often associated with sexual abuse, including aggression, withdrawal, anxiety and sexualised behaviours.
Teaching children to relax helps to create a context in which they can be helped to express their emotions and acquire cognitive coping skills. Both children (and parents) learn how to label the feelings associated with the abuse and to communicate them to others; they learn to identify maladaptive beliefs and attributions and replace them with those that are more accurate and effective. Depending on their age, children are taught to recognise the signs of anxiety and the internal and external factors that can trigger it, and helped to replace maladaptive responses with adaptive ones.
Unsurprisingly, children and parents may go to some lengths to avoid the reminders of what happened, which may well trigger post-traumatic stress symptoms or anxiety, but these 'safety behaviours' mean that children do not learn that these 'neutral' or 'now neutral' situations are non-threatening and they fail to experience 'coping'. Gradual exposure (or 'in vivo mastery'), therefore, is an important component.
TF-CBT incorporates a specific focus on the trauma itself. This enables the therapist to help the child identify and correct problematic assumptions and concerns that he or she might have as a result of what happened. The explicit focus on the traumatic experience(s) of sexual abuse is thought to help the child to process

their experiences in ways that prevent the continuation of intrusive thoughts and flashbacks that can be triggered by current events that themselves carry no threat.

Eye-Movement Desensitisation and Reprocessing (EMDR)

Shapiro's adaptive information processing (AIP) model posits that mental disorders result from memories of adverse past experiences that were inadequately stored in the memory (Shapiro 2001). Memories stored in a dysfunctional manner can be understood as containing disturbing feelings, thoughts, beliefs and physical sensations that cause continued distress and that may be triggered by present life experiences. Shapiro hypothesises that EMDR therapy facilitates the accessing of the traumatic memory network, so that information processing is enhanced, with new associations forged between the traumatic memory and more adaptive memories or information (Shapiro 1993; Shapiro 2001). These new associations are thought to result in complete information processing, reformulation of associated cognitions, desensitisation of emotional distress, and relief of accompanying physiological arousal, leading to the development of cognitive insights (see Oren 2012; Shapiro 2014; Shapiro 2017).

Systemic therapies

Generally, during treatment, the young clients are encouraged to share the difficult thoughts and feelings they may be experiencing because of the abuse. Family members are also encouraged to listen to each other's beliefs and interpretations about what has occurred. Drawings of genograms (family trees) are used to identify system relationships that need to be restored; and solution-focused ideas and coping skills are thought to ease guilt and stress with regard to how each family member can contribute to the family's functioning. The understanding of each other's meanings and the linking of such meanings with beliefs and interpretations about the family's problems are thought to facilitate the co-creation of more positive interactions between family members (Lorås 2017). More specifically, structured systemic therapies view system dysfunction as a result of a disorganised family structure. The therapist will try to restore the system's boundaries by questioning family members' interpretations around the dysfunction occurring as a result of the sexual abuse, the structure of the family and the beliefs network of the system. Strategic systemic models attribute families' problems to negative interactions between members. The therapist will try to improve these interactions by encouraging the members of the system to assess how the problems influence the system and how each member can contribute to make things better. Family members may create narratives that limit what they can do to address the family's difficulties. Social constructivist therapists will prevent the creation of these limitations by offering opportunities for open dialogue and the creation of narratives in which the family's difficulties are shown as an opportunity for change and moving forward (Tickle 2016).

Person-centred therapy

Research about how person-centred therapy ameliorates a patient's psychological distress is scarce. From a humanistic perspective, the process of change is most accurately conceptualised as a combination of consciousness raising and corrective emotional experiencing, which occurs within the context of a genuine empathic relationship characterised by unconditional positive regard (Cain 2001; Hofmann 2017; Prochaska 1999).

Common factors and common elements

Although each intervention approach hypothesises a particular set of processes whereby change is brought about, some writers argue that many therapies that appear to be distinct share common elements that account for their impact; for example psychoeducation, exposure, relaxation, etc. (Barth 2012). Others argue that the effectiveness of therapeutic approaches are primarily attributable to nonspecific factors in therapy, such as the nature of the therapeutic relationship (trusting, emotionally charged); the therapeutic context plus the client's belief that the therapist can help; a narrative that makes sense of the client's problems and a plausible means of dealing with them (see, for example, Field 1993; Jensen 2005). This review is not designed to explore these factors, but they will be discussed in relation to the findings.

Why it is important to do this review

Most studies assessing the effectiveness of psychotherapeutic interventions to treat the psychological consequences of sexual abuse in children and young people use pairwise meta-analyses (Benuto 2015; Corcoran 2008; Harvey 2010; Hetzel-Riggin 2007; Macdonald 2012; Parker 2013; Reeker 1997; Sánchez-Meca 2011; Trask 2011), which only compare two interventions. Since not all therapies have been assessed in head-to-head comparisons, studies' conclusions may only partially yield information needed to make informed decisions (Tonin 2017).

Network meta-analysis allows comparison of multiple treatments, using direct comparisons of interventions within randomised controlled trials (RCTs) and indirect comparisons across trials based on a common comparator (Hindryckx 2017). Network meta-analysis provides estimates of the effects of each intervention relative to every other, and allows calculation of the probability of one intervention being the best for a specific outcome (Caldwell 2010). No network meta-analysis has been conducted to assess the relative effectiveness of psychotherapeutic interventions drawn from psychodynamic, cognitive behavioural, systemic and humanistic theories, compared to other treatments or no treatment controls, to overcome psychological sequelae of sexual abuse in children and

young people up to 18 years of age. This review aims to bridge this gap and to provide an up-to-date account of what is known about what works for whom, for what outcomes, and under what circumstances for this group of children.

OBJECTIVES

To assess the relative effectiveness of psychosocial therapies, compared to other treatments or no treatment controls, to overcome psychological sequelae of sexual abuse in children and young people up to 18 years of age.

Secondary objectives

- To rank psychotherapies according to their effectiveness.
- To compare different 'doses' of the same intervention.
- To explore differences between subgroups of participants and assess the impact of moderator variables on treatment outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) that compare the focal intervention with an alternate psychological intervention, no treatment or a different amount (dose) of the focal intervention.

Types of participants

All children and adolescents up to 18 years of age who have experienced any kind of sexual abuse (see Description of the condition).

Types of interventions

Interventions of direct interest

Any psychosocial intervention, delivered by a trained professional in any setting or any format (individual or group), and at any 'dose' that is "designed to alleviate psychological distress, reduce maladaptive behaviour, or enhance adaptive behaviour through counselling, structured or unstructured interaction, a training program, or a predetermined treatment plan" (Weisz 1987). We will include interventions delivered to a child by, or through, a parent or other carer if these are concerned with addressing the consequences of sexual abuse for the child. We will exclude pharmacological interventions and will document interventions of which we were not aware but which we identified while conducting the review. We acknowledge that there may be interventions occurring in practice that have not been evaluated. We hope to include those in future updates of this review.

Experimental interventions

Any psychodynamic, cognitive behavioural, systemic and humanistic therapy delivered by a trained professional in any setting or any format (individual or group), and at any 'dose' (Weisz 1987). We will include group or individual interventions as well as interventions delivered to a child by, or through, a parent or other carer if these are concerned with addressing the consequences of sexual abuse for the child. For example:

- psychodynamic theory (therapies offered to the child or parent-child dyads);
- cognitive behavioural theory (trauma-focused cognitive behavioural therapy, cognitive behavioural therapy, abuse-focused cognitive behavioural therapy);
- humanistic theory (person-centred therapy, non-directive play therapy, self-help approaches); and
- systemic theory (family therapy, multigroup family therapy, family-based programmes).

We assume that any patient who meets the inclusion criteria is equally likely to be randomised to any of the eligible treatments. However, we will check the transitivity assumption, as stated in the 'Assessment of transitivity across treatment comparisons' section.

Comparator interventions

Focal intervention may be compared with any of the following.

- An alternate psychological intervention
- No treatment
- A different amount (dose) of the focal intervention

We will include focal interventions that are delivered in conjunction with another therapy (of any kind) if the adjunctive therapies (but not the focal therapy) are provided to the control group. In these circumstances, we will assume that the study measures the relative effectiveness of the only intervention that differs across the study arms (i.e. the focal intervention).

Types of outcome measures

We will estimate the relative rankings of the competing interventions according to the following outcomes (Macdonald 2016).

Primary outcomes

- Psychological distress/mental health, including post-traumatic stress disorder (PTSD; e.g. the Children's PTSD Inventory (Saigh 2000) or the Trauma Symptoms Checklist (Briere 1989)); depression (e.g. the Children's Depression Inventory (Kovacs 1992)); anxiety (e.g. State-Trait Anxiety Inventory for Children (Spielberger 1973)); and self-harm (e.g. item nine on the Child Depression Inventory (CDI) (Kovacs 1992)).*
- Behaviour, including sexualised (e.g. the Child Sexual Behavior Inventory (CSBI) (Friedrich 1992)), and internalising and externalising behaviours (e.g. the 'Externalising' subscale of the Child Behavior Checklist (CBCL) (Achenbach 1991)).*
- Social functioning, including attachment* (e.g. the Inventory of Parents and Peer Attachment (IPPA) (Armsden 1987)).
- Relationships with family and others, cognitive or academic attainment, and quality of life (e.g. the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (NHS Health Scotland 2006)).

* Please see paragraph two in the 'Summary of findings' section below.

Secondary outcomes

- Substance misuse (e.g. the Youth Risk Behaviour Survey (Brener 2004)).
- Delinquency (e.g. the Youth Risk Behaviour Survey (Brener 2004)).
- Resilience (e.g. the Children's Attributional Style Questionnaire (CASQ) (Thompson 1998)).
- Carer distress and efficacy (e.g. the Revised Scale for Caregiving Self-Efficacy (Steffen 2002)).

Rating scales

A wide range of instruments are available to measure the behavioural and psychological consequences of CSA (DSM-5; Deblinger 1989; Kendall-Tackett 1993; Nakamura 2009; OCECYMH 2014; Siddons 2004). We will include outcome data if instruments are reported to be reliable and valid, and either are self-reports or are completed by an independent assessor or relative. Variation in the timing of the follow-ups is expected, so we will analyse data in three categories: short term (one to three months following therapy), medium term (four to six months following therapy), and long term (six to 12 months following therapy).

Search methods for identification of studies

We will search for all possible comparisons formed by the interventions of interest.

Electronic searches

We will search the following databases and trial registers for relevant studies.

- Cochrane Central Register of Controlled Trials (CENTRAL; current issue), in the Cochrane Library, which includes the Developmental, Psychosocial and Learning Problems Specialized Register.
- MEDLINE Ovid (1946 onwards).
- MEDLINE Ovid In-Process & Other Non-Indexed Citations (current issue).
- Embase Ovid (1980 onwards).
- Allied and Complementary Medicine Database Ovid (AMED; 1985 onwards).
- Child Development & Adolescent Studies EBSCOhost (1970 onwards).
- CINAHL (Cumulative Index to Nursing and Allied Health Literature EBSCOhost; 1937 onwards).
- *Cochrane Database of Systematic Reviews* (CDSR, current issue), in the Cochrane Library.
- Conference Proceedings Citation Index - Science Web of Science (CPCI-S; 1990 onwards).
- Conference Proceedings Citation Index - Social Science & Humanities Web of Science (CPCI-SSH; 1990 onwards).
- ERIC EBSCOhost (Educational Resources Information Center; 1966 onwards).
- Electronic Theses Online Service, The British Library (EThOS; 1800 onwards).
- Health Technology Assessment Database (HTA; current issue; www.crd.york.ac.uk/CRDWeb).
- Epistemonikos (www.epistemonikos.org).
- SciELO Citation Index Web of Science (2002 onwards).
- Science Citation Index Web of Science (1970 onwards).
- Social Sciences Citation Index Web of Science (1970 onwards).
- ClinicalTrials.gov (current issue; clinicaltrials.gov).
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (current issue; www.who.int/ictrp/en).

The search strategy for MEDLINE can be found in Appendix 1. We will modify this strategy for use with other databases.

Searching other resources

We will check the references of previous reviews, meta-analyses and included studies, and will contact known experts in the field, to identify missing studies or additional unpublished or ongoing relevant studies. We will also run pre-publication searches in relevant databases to identify any reports of retractions or errata that impact the included studies.

Data collection and analysis

Selection of studies

At least two of the three review authors (PC, GM, WT) will independently screen the titles and abstracts of studies retrieved from the searches against the selection criteria (Criteria for considering studies for this review). We will eliminate studies deemed irrelevant by both review authors. We will obtain the full text of any title or abstract that one review author thinks might meet the inclusion criteria and assess it against the inclusion criteria. We will discuss any disagreements with the third author and, if agreement is not reached, we will either seek the information necessary to resolve the issue from the study authors, or consult the Cochrane Developmental, Psychosocial and Learning Problems Editorial base. We will record the reasons for excluding studies in a 'Characteristics of excluded studies' table. We will present our study selection process (along with number of records and studies, and reasons for exclusion of records at screening of full-text reports) in a PRISMA flow diagram (Moher 2009).

Data extraction and management

At least two of the three review authors (PC, GM, WT) will independently extract study data and enter data onto a structured, pilot-tested, Excel data collection form (Appendix 2). We will extract data on the following.

Outcome data

From each included study, we will extract relevant details on all primary and secondary outcome measures used, as defined by the review authors (PC, GM, WT); and length of follow-up and summary data, including means, standard deviations, confidence intervals (CI) and significance levels for continuous data, and proportions for dichotomous data.

Data on potential effect modifiers

From each included study, we will extract data on the following characteristics that may act as effect modifiers.

- Study characteristics (geographical location of study; study design; study duration; details of attrition; risk of bias concerns; service setting (e.g. hospital or community, research facility or community agency); whether the researchers were members of the treatment agency or independent or external; proportion of families referred or approached who agreed to be randomised; and characteristics of the therapists (e.g. discipline, level of qualification or student, years of experience)).
- Participant characteristics (number randomised; nature and duration of sexual abuse, including sexual exploitation; age of participants; specific diagnosis; comorbidities; gender distribution; sexual orientation).
- Intervention characteristics (intervention components; format and timing of psychological therapy; duration; frequency; concurrent interventions; whether the treatment is manualised, semi-structured or unstructured treatment; if participants were required to attend a set number of sessions; and if participants were paid).
- Comparison characteristics (format, frequency and duration).

Other data

From each included study we will extract data on the following additional information.

- Study author(s), year of publication, citation and contact details.
- Sources of funding and other potential commercial interests.

We will resolve doubts and disagreements by consensus, by seeking further information from study authors, or by involving an external person, as appropriate.

Assessment of risk of bias in included studies

Using the data extraction form, two review authors (PC, WT) will independently assess each study for risk of bias. We will assign each of the included studies to one of the following categories, as suggested in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017).

- High risk of bias (plausible bias that seriously weakens confidence in the results).
- Low risk of bias (plausible bias unlikely to seriously alter the results).
- Unclear or unknown risk of bias (plausible bias that raises some doubts about the results).

We will base the 'Risk for bias' assessment on the following domains, outlined in the *Cochrane Handbook for Systematic Reviews of Interventions (*Higgins 2017).

Selection bias

- Random sequence generation (was the allocation sequence adequately generated?)
- Allocation concealment (was allocation adequately concealed?)

Detection bias

- Blinding of participants and personnel (was knowledge of the allocated intervention adequately prevented during the study?)

- Blinding of outcome assessors (was knowledge of the allocated intervention adequately prevented during the study?)

Performance bias

Therapist and researcher allegiance, treatment fidelity (was treatment fidelity adequately monitored?)

Attrition bias

- Incomplete outcome data (were incomplete outcome data adequately addressed?)

Reporting bias

- Selective outcome reporting (are reports of the study free of suggestion of selective outcome reporting?)

Other sources of bias

- Was the study apparently free of other problems that could put it at a high risk of bias?

Review authors will resolve disagreements by discussion until they reach a consensus. Where this is not possible, the third member of the review team will arbitrate.

Measures of treatment effect

Relative treatment effects

We will estimate the pairwise relative treatment effects of the interventions by calculating effect sizes appropriate for the type of outcome data provided. For binary outcomes, we will use the odds ratios (OR) with 95% confidence intervals (CI). For continuous data (e.g. data on standardised measures), we will use the standardised mean difference (SMD) with 95% CI. If studies use the same measure to assess the same outcome, we will use the mean difference (MD) with 95% CI (Higgins 2017).

Relative treatment ranking

We will also estimate the ranking probabilities for each treatment. This is the probability that each treatment is the first, second, third, etc., best in the network. We will obtain a treatment hierarchy using the surface under the cumulative ranking curve (SUCRA) and mean ranks. SUCRA can also be expressed as percentage and interpreted as the percentage of efficacy or safety of treatment that would be ranked first without uncertainty (Chaimani 2013).
We will use mean final values. Where scales measure the same outcomes in different ways, we will use standardised mean differences in order to combine results across scales. If an outcome is assessed using a measure with subscales, we will use the total score, providing the full scale addressed the outcome of interest. Otherwise, we will use the most relevant subscore.

Unit of analysis issues

Cluster randomised trials

If we find studies that randomise groups rather than individuals, we will proceed as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

- When it is not clear if study authors controlled for clustering effect when presenting their results, we will contact them for further information.
- If study authors did not control for clustering effect, we will request individual participant data (IPD) to calculate an estimate of the intra-cluster correlation coefficient (ICC). If we obtain the IPD, we will report it using the Preferred Reporting Items for a Systematic Review and Meta-analysis of Individual Participant Data Checklist (PRISMA-IPD), and will analyse the IPD from all eligible studies within the same model simultaneously, accounting for clustering of participants within each study (Veroniki 2016b).
- If individual participant data are not available, we will use an estimate of the ICC from similar studies.
- If an estimate of the ICC is not available from similar studies, we will seek statistical advice to obtain an estimate of the ICC. We will reanalyse studies' data and will try to correct the analysis.
- We will use Review Manager 5 (RevMan 5) to analyse effect size (Review Manager 2014); and CI using the generic inverse variance method (Higgins 2011).

Cross-over trials

If we find studies in which participants receive the control and the intervention but in different order, we will include these studies but will only use data from the first period (Higgins 2011).

Studies with multiple treatment groups

For studies including multiple treatment groups, we will include each pairwise comparison separately. When variables are binary, we will divide the shared intervention group evenly among the comparisons (only in pairwise comparisons); when variables are continuous, we will divide only the total number of participants - we will leave the means and standard deviations unchanged. This will avoid double counting the participants in the pooled estimate of treatment effect, while retaining information from each arm of the trial. The network meta-analysis will consider the correlation between the effect sizes from multi-arm studies (Higgins 2011).

Dealing with missing data

We will not exclude studies due to missing data. We will follow the principles in the *Cochrane Handbook for Systematic Reviews of Interventions* to handle missing data (Higgins 2011).

First, we will endeavour to contact the original investigators to request the missing data, beginning with the contact author. We will pose the questions in ways that minimise biased responses from the study authors.

For dichotomous outcome data missing at follow-up, we will simulate intention-to-treat analyses with imputation, using the following assumptions: i) that all missing cases had positive outcomes; ii) that all missing cases had negative outcomes. We will undertake sensitivity analyses (Sensitivity analysis), comparing results with imputed data to those obtained under the assumption that data are missing at random.

For continuous data, we will extract all available data, including data from available cases, from completers and last observation carried forward. We anticipate that available case data will be those most commonly encountered, in which event we will conduct a sensitivity analysis by assuming that data are missing at random and that reported means and standard deviations apply to missing cases (Sensitivity analysis).

Where studies have missing summary data, such as missing standard deviations, we will obtain them from the standard error of a mean by multiplying by the square root of the sample size. If the standard error is not available, we will use the CI. If the sample is bigger than 100, for example, we will obtain the SD by dividing the length of the CI by 3.92 if a 95% CI, by 3.29 if a 90% CI, or by 5.15 if a 99% CI, then multiplying by the square root of the sample size. Where sample sizes are smaller than 60, we will change the numbers 3.92, 3.29 and 5.15 to larger numbers specific to the t distribution. These can be obtained from tables of the t distribution with degrees of freedom equal to the group sample size minus 1 (Higgins 2017).

Data synthesis

Methods for direct treatment comparisons

Since we expect clinical heterogeneity between included studies, we will perform a random-effects meta-analysis using RevMan 5 (Review Manager 2014). We also will calculate an average treatment effect across the studies for each available comparison. For dichotomous outcomes, we will calculate the average OR with 95% CI. For continuous outcomes, we will calculate the average SMD (or MD if all studies used the same scale) with 95% CI. We will use the modified Hartung‐ Knapp/Sidik‐ Jonkman (HKSJ) method to calculate the 95% CI in each pairwise comparison (Knapp 2003; Veroniki 2019).

Methods for indirect and mixed comparisons

We will conduct a random-effects model network meta-analysis in STATA (StataCorp 2013), using the suite of programs developed by White 2015. We will report the average effect estimate and its 95% CI.

We will present the ranks of the treatments per outcome in rankograms (Salanti 2011); and the values of the SUCRA estimate in a rank heat plot (Veroniki 2016a). NMA models typically employ a single heterogeneity parameter. We will report it and, for dichotomous outcomes, we will judge its magnitude against the distribution of values typically found in Cochrane Reviews, based on Turner's estimate (Turner 2012).

Assessment of statistical heterogeneity

Assumptions when estimating heterogeneity

In a standard pairwise meta-analysis, we will estimate separate heterogeneity variances for each pairwise comparison. In a network meta-analysis, we will assume a common estimate for heterogeneity variance across different comparisons.

Measures and tests for heterogeneity

We will assess statistically the presence of heterogeneity within each pairwise comparison using the following tests and measures (Deeks 2017).

- Funnel plots: asymmetric funnel plots will indicate statistical heterogeneity.
- Chi^2 statistic: P value < 0.05 will indicate statistical heterogeneity.
- Overlap of the CI for the results: poor overlap will indicate statistical heterogeneity.
- I^2 statistic (percentage of variability in effect estimates that is due to heterogeneity rather than sampling error), to quantify inconsistency across studies. This indicator takes values between 0% and 100% and describes the percentage of total variation across studies caused by heterogeneity rather than chance. Negative values of I^2 will be equalised to zero and its interpretation will be guided by the following thresholds.
    - 0% to 40%: not important.
    - 30% to 60%: moderate heterogeneity.
    - 50% to 90%: substantial heterogeneity.
    - 75% to 100%: considerable heterogeneity.
- Tau^2, an estimate of between-studies variance calculated using the Paule and Mandel (PM) method, which is suitable for both dichotomous and continuous outcomes (Paule 1989; Veroniki 2016c).

We will assess the presence of statistical heterogeneity in the entire network using the magnitude of the heterogeneity variance parameter (τ^2) estimated from the NMA models. For dichotomous

outcomes, the magnitude of the heterogeneity variance can then be compared with the empirical distribution as derived by Turner 2012. We will compare continuous outcomes against the predictive distributions reported by Rhodes 2015. We will also estimate a total I^2 value for heterogeneity in the network (Savović 2012).

Assessment of clinical and methodological heterogeneity within treatment comparisons

We will assess the presence of clinical and methodological heterogeneity within each pairwise comparison by comparing population characteristics (participants, interventions, outcomes) and trial characteristics (study design and risk of bias) across all eligible trials.

Assessment of transitivity across treatment comparisons

Transitivity refers to the distribution of potential effect modifiers (participants' age, interventions' settings, interventions' durations, sample size, etc.) being similarly distributed across comparisons in the network (Cipriani 2013). We will assess transitivity by visually inspecting that the characteristics of the studies that might modify the effect of the treatment are similarly distributed among trials; for example, whether a psychotherapy is administered the same way in studies comparing it to placebo and in studies comparing it to a different psychotherapy. Statistically, we will assess the lack of transitivity by contrasting the indirect and direct estimates, and performing a test of the differences between closed loops as suggested by Bucher 1997 and Salanti 2009. We will report the percentage of inconsistent loops in the network.

Assessment of statistical inconsistency

Local approaches for evaluating inconsistency

We will infer the presence of inconsistency in each loop of the network by evaluating the magnitude of the difference between direct and indirect estimates (inconsistency factor) and their 95% CI. We will assume a common heterogeneity estimate and will present the results in a forest plot using the command ifplot in STATA (Chaimani 2015; Veroniki 2013).

Global approaches for evaluating inconsistency

We will check the assumption of consistency of the entire network through the design × treatment model based on the Chi^2 test. We will perform this analysis through the command mvmeta in STATA (Higgins 2012).

Investigation of heterogeneity and inconsistency

Should there be a sufficient number of studies for the primary outcomes, we will perform subgroup and meta-regression analyses with the following explanatory variables (Higgins 2017).

- Children's age
- Children's gender
- Composite of intensity of the treatment (a combination of frequency × length)

We will not perform subgroup analyses by type (psychodynamic, cognitive behavioural, systemic or humanistic) or modality (group or individual) of therapy. The former, because we are combining direct and indirect evidence on comparisons made between all of the types of treatments. The latter, because psychodynamic and family therapy are unlikely to be delivered in group and individual formats, respectively.

Sensitivity analysis

We will assess the robustness of findings by performing the following reanalyses.

- Reanalysis using a fixed-effect model.
- Reanalysis without imputing data.
- Reanalysis restricting the analysis only to studies considered to be at low risk of selection and detection bias (i.e. adequate allocation sequence generation, adequate allocation concealment, blinding of assessor).
- Reanalysis excluding group therapy studies.
- Reanalysis excluding studies in which a concomitant pharmacotherapy is allowed.

We will present the results of these analyses in a summary table.

Summary of findings

We will include tables reporting the characteristics, risk of bias and treatment effect sizes of the included studies.
We will create 'Summary of findings' tables for the comparisons and outcomes marked with an asterisk under the Types of outcome measures section at two time points: immediately and up to one year after the treatment.
Finally, we will use the Confidence in Network Meta-Analysis online tool (CINeMA) based on the GRADE approach proposed by the GRADE Working Group, to make judgements about how the statistical contributions of the direct comparisons contribute to the credibility of NMA treatment effects (CINeMA 2017; Salanti 2014).

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

MEDLINE Ovid

1 Child Abuse, Sexual/
2 (child$ adj5 sex$).tw,kf.
3 1 or 2
4 Sex Offenses/
5 Rape/
6 INCEST/
7 (sex$ adj5 abuse$).tw,kf.
8 (sex$ adj5 offen$).tw,kf.
9 (sex$ adj5 assault$).tw,kf.
10 (sex$ adj5 coerc$).tw,kf.
11 (sex$ adj5 exploit$).tw,kf.
12 (sex$ adj5 (in-appropriate or inappropriate)).tw,kf.
13 (sex$ adj5 victim$).tw,kf.
14 (sex$ adj5 violen$).tw,kf.
15 (rape$ or molest$).tw,kf.
16 (incest$ or rape$ or molest$).tw,kf.
17 or/4-16
18 infant/
19 exp Child/
20 Adolescent/
21 (baby or babies or boys or girls or infant$ or preschool$ or pre-school$ or child$ or teen$ or adolescen$ or youth$ or young people$ or young person$).tw.
22 or/18-21
23 17 and 22
24 3 or 23
25 exp psychotherapy/
26 mind body therapies/
27 (psycho$ therap$ or psychotherap$).tw,kf.
28 (psychoanalytic$ or psycho-analytic$ or psychodynamic$ or psycho-dynamic$).tw,kf.
29 Cognitive Therapy/
30 ((cognitive-behav$ or cognitive or cognition) adj3 (approach$ or program$ or intervention$ or therap$ or treatment$)).tw,kf.
31 CBT.tw,kf.
32 counsel?ing.tw,kf.
33 (psychodrama or acting out or role play).tw,kf.
34 (meditat$ or mindfulness$ or mind training).tw,kf.
35 (Relax$ adj3 (training$ or treatment$ or therap$)).tw,kf.
36 (multisystemic or multi-systemic).tw,kf.
37 ((psychosocial or psycho-social or psychoeducation$ or psycho-education$) adj3 (approach or intervention$ or program$ or support$ or therap$ or treatment$)).tw,kf.
38 ((family or group or systemic$ or multimodal$ or multi-modal$) adj3 (program$ or intervention$ or therap$ or treatment$)).tw,kf.
39 exp Behavior Therapy/
40 (behavio?r$ adj3 (approach$ or program$ or intervention$ or therap$ or treatment$)).tw,kf.
41 ((exposure or abreaction or desensitization) adj3 therap$).tw,kf.
42 ("Eye Movement Desensitization and Reprocessing" or EMDR).tw,kf.
43 ((existential or gestalt or humanistic or milieu or person-centred or residential) adj therap$).tw,kf.

44 (process-experiential or transactional analysis or non-directive).tw,kf.
45 (therapeutic adj (alliance or relationship)).tw,kf.
46 Feedback, Psychological/
47 ((biofeedback or feedback or imagery) adj3 (intervention$ or therap$ or treatment$ or train$)).tw,kf.
48 (hypnosis or hypno-therapy or hypnotherapy or breathing exercise$).tw,kf.
49 object attachment/
50 ((attachment or bond$) adj3 (infant$ or child$ or mother$ or maternal$ or father$ or paternal$ or parental$))tw,kf.
51 ((solution focus$ or trauma$ or talking) adj3 therap$).tw,kf.
52 dialectical behaviour therapy.tw,kf.
53 "acceptance and commitment therapy".tw,kf.
54 sensory art therapies/
55 ((art or drama or music or narrative or play$ or sensory) adj1 (program$ or intervention$ or therap$)).tw,kf.
56 Third wave.tw,kf.
57 or/25-56
58 24 and 57
59 randomized controlled trial.pt.
60 controlled clinical trial.pt.
61 randomi#ed.ab.
62 placebo$.ab.
63 drug therapy.fs.
64 randomly.ab.
65 trial.ab.
66 groups.ab.
67 or/59-66
68 exp animals/ not humans.sh.
69 67 not 68
70 58 and 69

Appendix 2. Data extraction form

Source	Study identifier (ID)
	Report ID
	Review author ID
	Citation
	Contact details
	Geographical location of study
	Study duration
Eligibility	Confirm eligibility for review
	Reasons for exclusion
Methods	Study design

(*Continued*)

	Total study duration
	Allocation sequence concealment
	Blinding
	Other concerns about bias
Participants	Total number
	Setting
	Diagnostic criteria
	Age
	Gender
	Country
	Comorbidity
	Ethnicity
	Sociodemographic
	Date of study
Interventions	Total number of interventions groups
For each intervention and comparison group	Specific intervention
	Intervention details (e.g. components, format and timing of psychological therapy, duration, frequency, concurrent interventions) Sufficient detail for replication?
	Integrity of intervention (compliance or fidelity)
Outcomes	Outcomes and time points (i) collected (ii) reported
For each outcome of interest	Outcome definition (with diagnostic criteria)
	Unit of measurement
For scales	Upper and lower limits and whether high or low score is good
Results	Number of participants allocated to each intervention group

(*Continued*)

For each outcome of interest	Sample size for analyses (if different from above)
	Missing participants (details of attrition)
	2×2 table (dichotomous data)
	Proportions (dichotomous data)
	Means (continuous data)
	Standard deviations (continuous data)
	Estimate of effect with confidence interval
	P value
	Significance levels (continuous data)
	Subgroup analysis
Miscellaneous	Funding source
	Potential commercial interests
	Key conclusions of the study authors
	Miscellaneous comments from the study authors
	References to other relevant studies
	Correspondence required
	Miscellaneous comments by the review authors

CONTRIBUTIONS OF AUTHORS

PC drafted the protocol. All authors reviewed and approved the final version of the protocol. WT and GM are the guarantors of the protocol.

DECLARATIONS OF INTEREST

Paola Caro: none known.

William Turner is an Editor with Cochrane Developmental, Psychosocial and Learning Problems (CDPLP).

Geraldine Macdonald is the Coordinating Editor of CDPLP.

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